United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-06

☒ Original ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment
EP-W-11-020	02/1/2015 to 01/31/2016 ☐ Base ☒ Option Period Number: IV	EDSP Study Review and Support Activities

Contractor: CDM Federal Programs Corporation

Specify Section and Paragraph of Contract SOW:

Purpose:
☒ Work Assignment Initiation ☐ Work Assignment Close-Out
☐ Work Assignment Amendment ☐ Incremental Funding
☐ Work Assignment Approval

Periods of Performance: From: Date of CO Signature To: 01/31/2016

Comments:
The estimated level of effort for this work assignment is 1,250 hours.

☐ Superfund

Accounting and Appropriations Data

☐ Non-Superfund

Line	DC (Max 6)	Budget/FYs (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 02/01/2015 To 01/31/2016 Previously Approved	$0.00	0
This Action		
Total		

Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name: Tanisha Brockett (Signature) (Date)	Branch/Mail Code: 7507P Phone Number: (703) 305-6937 Fax Number:
Project Officer Name: Tanisha Brockett (Signature) (Date)	Branch/Mail Code: 7507P Phone Number: (703) 305-6937 Fax Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: Fax Number:
Contracting Officer Name: Christine Edwards (Signature) 4/29/2015 (Date)	Branch/Mail Code: 3803R Phone Number: (202) 564-2182 Fax Number:

Contractor Acknowledgement of Receipt and Approval of Workplan *(Signature and Title)* | Date

EPA Form 1900-69 (Rev. 07-95)

Contract #EP-W-11-020
Work Assignment #4-06
Statement of Work

Title:	Endocrine Disruptor Screening Program (EDSP) Study Review and Support Activities
Period of Performance:	February 1, 2015 – January 31, 2016
Level of Effort:	1,250 hours

I. Background:

As required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups.

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect. In some cases, other guideline studies, non-guidelines studies, or Other Scientifically Relevant Information (OSRI) may be submitted to provide information of possible interest.

II. Scope of Work:

Under Task A of the contract Statement of Work, the contractor shall provide support primarily in the area of review and evaluation of available data pertaining to the effects, chemistry, and fate of pesticides or other chemicals (including the evaluation of environmental monitoring data), assessing environmental risk from pesticides, and the assessment of pesticide effects, fate, and transport in the environment. This work assignment will focus exclusively on studies submitted as part of the EDSP, and may include the use of special software provided by EPA designed to

produce Data Evaluation Records (DERs). Contractor support may be requested for additional activities related to such special software and/or databases to be used under the EDSP; these activities may include but are not limited to beta testing of applications, quality assurance/quality control (QA/QC), data entry, and preparation of reference materials, as needed.

The contractor shall, upon request by EPA, collect data from the open literature or from other sources designated by EPA and shall review these data as well as all other effects, fate, and transport studies provided to the contractor by EPA. The reviews shall: (1) evaluate individual studies of chemicals subject to the EDSP and will identify any variance from published guidelines/standard evaluation procedures (SEPs)/data review guidelines, etc., (2) and evaluate data from the open literature or other sources when specifically requested by EPA, and (3) review and synthesize information from multiple data sources as designated by EPA. EDSP policies and procedures, including relevant test guidelines, SEPs, and DER templates (also called "Study Profiles"), are publicly available online at http://www.epa.gov/endo.

The work assignment manager or contracting officer's representative (COR) will make available to the contractor the data, studies (for preparation of a DER), and information which is to be reviewed, with the occasional exceptional circumstance where the COR requests that the contractor collect and aggregate extant data or studies from open literature or other sources. The studies and data will be provided in printed form (originals or reprints of each study) and/or electronic form. Due dates for each data package and/or assessment and/or project shall be negotiated between the COR and the contractor.

The contractor will fully substantiate and document all work efforts in this regard so that EPA may critically analyze and approve/disapprove any recommendation, options, alternatives or courses of action flowing from the contractor's work effort.

Communications shall take place as necessary to resolve technical, format and entry questions. Communication may be via phone calls, FAX, E-mail, and/or other types of progress reports. Face-to-face meetings or conference calls will be held as deemed necessary.

III. Deliverables:

As mentioned in the Scope of Work, the due date will be negotiated between the COR and the contractor. A standard review of a study generally takes eight weeks after receipt to complete. However, on occasion, the contractor will be required to perform an enhanced review. This enhanced review will require that the due date and/or schedules be changed or accelerated. Enhanced review of studies and data is required under Section 33 of FIFRA (as added by subsection (f)(2) of the Pesticide Registration Improvement Act of 2003).

All DERs shall be delivered by courier or Federal Express. Deliverables shall be a hardcopy and on a CD. A hardcopy of the associated Green Sheet shall also accompany the DER. Each CD shall include the DER, any input or output files used for statistical analysis, detailed calculations (such as a spreadsheet) that support the analysis in the DER, any input and output files for software (DER Composers) that may be used to create the DER (including XML files, if

applicable), and any requested electronic data entry submissions. When necessary, deliverables will be accepted via email.

IV. Quality Criteria:

The contractor shall submit all deliverables in Microsoft Word® (*.docx) and Excel (*.xlsx or *.xlsxm), unless otherwise specified. Input files may be provided in the file format (*e.g.*, ASCII, CSV, XML, *etc.*) used with the designated software. All tables, graphs, diagrams, etc. shall be developed using programs that allow for them to be easily imported into, and edited within, Microsoft Word® and Excel. All deliverables shall be clearly written, concise, and free of spelling and grammatical errors. (Note: Although EFED understands that there are nuances in spelling and grammar that may prevent documents from being 100% error free, there must be evidence that, at a minimum, a spell and grammar check was run, and that the contractor made an honest effort to produce error-free deliverables for EFED.)

Unless otherwise stated in a technical direction, EFED's minimum data quality criteria are 1) > 95% accuracy in all data summarization table entry, where all values and their accompanying units entered by the contractor into the summarization tables match exactly with those in the source data (e.g. DERs) 2) >95% accuracy between text and data tables, so that any values and their units referenced in the text are identical to those that appear in the data summarization tables, and 3) all relevant data and interpretation thereof correspond to the format and language style of any example(s) provided, to the extent instructed by EFED. Any electronic data spreadsheets provided to the contractor as supplements to a study report should be cross-referenced, by the contractor, with the certified data in the study report to ensure accuracy.

It is expected that the contractor shall approach each assignment as being unique; therefore, wherever examples, template, formats, etc. have been provided, the contractor shall generally follow them in such a way to ensure that all salient points pertaining to the particular chemical being assessed are included or added.

V. Reporting Requirements:

A work plan shall be submitted within 15 days of receipt of the approved work assignment as required in the contract. A final work plan shall be submitted within 5 days of receiving comments on a proposed work plan. A work plan is a formal document describing in comprehensive detail the necessary technical activities, staffing requirements, and QA/QC activities that shall be implemented to ensure that the results of the work performed will satisfy the needs and quality criteria identified in the work assignment. The staffing plan shall be written in accordance with all applicable elements (i.e. A1-A9, B9, B10, C1-C2, and D1-D3) of the EPA/QA R-5 document, EPA Requirements for Quality Assurance Project Plans, in consultation with the EPA/QA G-5 guidance document (USEPA, 2001; 2002). Within the staffing plan, the contractor shall clearly identify any points of clarification or additional information needed, which were not already addressed in the statement of work. This work plan shall also clearly indicate the contractor's proposed staffing levels and cost estimates for the work to be performed under this technical direction. The contractor shall indicate any proposed modifications to the time frames specified by EFED, with reasons for the proposed changes.

Written monthly progress reports shall include a detailed breakdown of costs and hours by task, and a description of tasks which were initiated or completed, and any problems which arose, as required in the contract.

VI. Schedule of Deliverables:

Work Plan	15 days after receipt of WA
Revised Work Plan	5 days after receipt of comments
Review of DERs	See Section III above